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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|-------------------------|------------------|
| 09/454,868 | 12/03/1999 | BARRY S. BROWN | DM-7029 | 4342 |
| 23914 | 7590 | 12/15/2003 | EXAMINER | |
| STEPHEN B. DAVIS | | | GUCKER, STEPHEN | |
| BRISTOL-MYERS SQUIBB COMPANY | | | ART UNIT | PAPER NUMBER |
| PATENT DEPARTMENT | | | | |
| P O BOX 4000 | | | 1647 | |
| PRINCETON, NJ 08543-4000 | | | DATE MAILED: 12/15/2003 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

KDP

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|------------------------------|----------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/454,868 | BROWN ET AL. | |
| | Examiner Stephen Gucker | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 August 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 23 and 24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 23 and 24 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. The "Brief Description of the Figures" section of the instant application is missing its heading and the description for Figures 1-4 must include a description for each of the individual panels found in the figures. Appropriate correction is required.
4. *Applicant's correction filed 8/12/03 was not entered because there is no paragraph beginning on line 7 and ending on line 24 on page 6 of the instant specification.*
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claims recite a method of administering a therapeutically effective amount of a compound which, as amended, is identified by contacting said compound with a transfected cell that stably coexpresses KCNQ2 and

KCNQ3 polypeptides, wherein the KCNQ2 and KCNQ3 form a potassium channel and measuring the activity of the potassium channel. Although the amended claims are process claims, they recite the use of a product which is defined by a process, i.e. a product by process. A product is properly defined by a process when the process steps define the structure of the product, e.g. rubber obtained by vulcanizing is structurally different than nonvulcanized rubber. The amended claims, however, do not recite the use of a compound by a process of making a compound, but the use of a compound that is identified by a process of screening, which merely identifies a compound with certain inherent characteristics, i.e. interacting with transfected potassium channels in such a way that the activity of the potassium channels are affected and measured. The genus of compounds so identified is not physically created or altered by the screening process. Therefore, the process does not describe the product or compound. The product by screening process to identify compounds to be used in the instant claims fail to adequately describe the full genus of compounds that could be used in the instant methods, which are not methods of screening, but methods of treatment. The specification only describes the examples of TEA, which has poor affinity and is not specific for the recited potassium channel, Iinopirdine, and XE991. It does not adequately describe the functional and necessary core chemical structure or structures which would adequately describe the full genus of compounds that would meet the instant claim limitations of interacting with the recited potassium channel. Therefore, the inventors did not have at the time the application was filed a full and adequate

description of the genus of compounds that could be used in the claimed methods of treatment.

6. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Earl et al. (U.S. Patent No. 5,173,489; "Earl"). Earl discloses linopirdine (3,3-bis(4-pyridinylmethyl)-1-phenylindolin-2-one) (column 61, line 5 to column 62, line 68) and methods of treating neurological or neurodegenerative disorders such as Alzheimer's disease (column 1, lines 16-51; column 2, line 66 to column 3, line 35) by administering linopirdine. The use of linopirdine has the inherent property of acting as an antagonist to KCNQ2/KCNQ3 channels as taught by the instant disclosure and meets all the limitations of claims 23 because the use of linopirdine would inherently meet the assay limitations as taught by the instant disclosure.

7. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Dailey et al. ("Dailey") in light of Rundfeldt et al. ("Rundfeldt"). Dailey discloses methods of treating epilepsy-prone rats with (N[2-amino-4-(4-fluorobenzylamino)-phenyl]carbamic acid ethyl ester dihydrochloride), otherwise known as the anticonvulsant retigabine (abstract of Dailey and see page 73 of Rundfeldt). Retigabine has the inherent property of acting as an agonist to KCNQ2/KCNQ3 channels as shown by Rundfeldt (abstract). Retigabine meets all the limitations of claim 24 because the use of retigabine would inherently meet the assay limitations as taught by Rundfeldt. Note that Rundfeldt need not be prior art as the reference is only being used to prove that retigabine has the inherent property of modulating KCNQ2/KCNQ3 channels.

8. Applicant's arguments filed 8/12/03 against both prior art rejections set forth above have been fully considered but they are not persuasive. The amended claims recite a method of administering a therapeutically effective amount of a compound which, as amended, is identified by contacting said compound with a transfected cell that stably coexpresses KCNQ2 and KCNQ3 polypeptides, wherein the KCNQ2 and KCNQ3 form a potassium channel and measuring the activity of the potassium channel. Although the amended claims are process claims, they recite the use of a product which is defined by a process, i.e. a product by process. A product is properly defined by a process when the process steps define the structure of the product, e.g. rubber obtained by vulcanizing is structurally different than nonvulcanized rubber. The amended claims, however, do not recite the use of a compound by a process of making a compound, but the use of a compound that is identified by a process of screening, which merely identifies a compound with certain inherent characteristics, i.e. interacting with transfected potassium channels in such a way that the activity of the potassium channels are affected and measured. The genus of compounds so identified is not physically created or altered by the screening process. Therefore, the process does not define the product or compound. The product's or compound's structural and chemical characteristics and properties remain inherent to the product or compound identified by the screening process. The process only identifies the inherent activity of the compound and is given patentable weight only to the extent that the compound cited in the rejection must be consistent with the activity being screened and not to the extent that the product must be specifically identified by the recited screening process.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Gucker

12/10/03

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600